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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,133	12/05/2001	Mark Ledebner	VPI/00-126 US	8058

7590

07/12/2005

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,133	Applicant(s) LEDEBOER ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5-23-05 (RCE).
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,17,20 and 21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-6,17,20 and 21 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Soa

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-23-05 has been entered.

Claims 7-16, 18 and 19 are cancelled.

Claims 1-6, 17, 20 and 21 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. **Lack Antecedent Basis:** Claims 4 and 5 recite the limitation "cyclohexyl" for R^1 . There is insufficient antecedent basis for this limitation in claim 1. Note, in claim 1, R^1 can be $T_{(n)}-Ar^1$. However, the definition of Ar^1 does not include cyclohexyl, which is a non-aromatic group.

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b. **Lack Antecedent Basis:** Claim 6 recites species having R¹ as a "cyclohexyl" group (e.g., compound no. II-37 – II-51, II-65 – II-75, II-94 – II-96, II-104 – II-106, II-112). There is insufficient antecedent basis for those species in claim 1. Note, in claim 1, R¹ can be T_(n)-Ar¹. However, the definition of Ar¹ does not include cyclohexyl, which is a non-aromatic group.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5, 17, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5 and 12 of U.S. Patent No. **6,884,804 B2**. Although the conflicting claims are not identical, they are not patentably distinct from each other because formula I of US'804 overlaps with the instant formula I when the disclosed variables have the following meaning:

- i. R^3 is hydrogen, which would make the positions of G and R^2 equivalent through an axis of symmetry.
- ii. G is $-XR$; wherein X represents C_{1-4} alkylidene in which one or two units can be replaced by $-S-$, $-SO-$, $-SO_2-$, $-O-$, or $-NH-$, and R is hydrogen; thus, $-XR$ is equivalent to the instant variable R^2 as $-CH_2SR$, $-CH_2S(O)_2R$, $-CH_2OR$ group, $-CH_2NHR$;
- iii. R^2 is hydrogen or C_{1-8} aliphatic group, which is equivalent to the instant variable G as hydrogen or $-R$ (an aliphatic group);
- iv. A is N, which gives *(pyrimidin-2-yl)-NH-*, which is equivalent to the instant Q-NH;
- v. R^1 is $T_{(n)}-R$ or $T_{(n)}$ -ring; wherein the ring is selected from *phenyl*, *pyridyl*, *naphthyl*, *quinolinyl*.

The disclosed formula (I) differs from the instant formula (I) by not having R^1 representing *hydrogen*, or $CONH_2$. Also, the scope of the instant R^2 is more extensive than the scope of the disclosed variable G.

However, it would have been within the level of the skilled chemist to recognize that when R^3 is hydrogen, then formula (I) of US'804 is a subgenus of the instantly claimed formula (I). Thus, at the time that the invention was made, it would have been obvious to make and use compounds of the instant formula (I) in view of the subgenus claimed in US'804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Anantanarayan et. al.** (US 6,514,977 B1). On columns 941 & 942, Anantanarayan et. al. disclose Scheme C-11, which is the process of making a 2-substituted pyrimidinylpyrazole of formula Cxv. Said formula generically encompasses the instantly claimed formula I having the following substituents:

- i. R^1 is hydrogen;
- ii. R^2 is R, which is an *aliphatic group substituted* with NH_2 ; or R is $-(CH_2)_2-NH_2$;

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iii. G is hydrogen;

iv. R^3 is hydrogen.

Although formula Cxv does not appear to have definitions for its variables, said formula is a subgenus of the disclosed formula I, which has description on columns 23-27. From said description, it can be deduced that variable R_{309} of formula Cxv is actually R^4 of the disclosed formula I, which can be hydrogen – corresponding to the instant variable G. Also, the variable R of formula Cxv is actually the *amino* group on R^3 of formula I – corresponding to the instant $NH-R^1$ wherein R^1 is hydrogen.

The disclosed compounds can treat diseases mediated by p38 kinase. Thus, from the subgenus of formula Cxv, the skilled medicinal chemist would have been motivated to select and make some compounds of the instant formula I because one would have expected those compounds to treat diseases mediated by p38 kinase as well.

Therefore, at the time that the invention was made, it would have been obvious to make and use compounds claimed herein in view of the teaching above.

5. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Anantanarayan et. al.** (WO 98/52940). On page 320, Anantanarayan et. al. disclose Scheme C-4, which is the process of making a 2-substituted pyrimidinylpyrazole of formula C-vi. Said formula generically encompasses the instantly claimed formula I having the following substituents:

i. R^1 is hydrogen;

- ii. R^2 is R, which is an *aliphatic group substituted* with NH_2 ; or R is $-(CH_2)-NH_2$;
- iii. G is hydrogen or alkyl;
- iv. R^3 is hydrogen.

Although formula C-vi does not appear to have definitions for its variables R^2 and R^3 , said formula is a subgenus of the disclosed formula I, which has description on pages 82-84. In said description, R^2 can be hydrogen – corresponding to the instant variable G. Likewise, R^3 of the disclosed formula I can be *pyrimidinyl* substituted with an *amino* group – corresponding to the instant $-NH-R^1$ wherein R^1 is hydrogen.

The disclosed compounds can treat diseases mediated by p38 kinase. Thus, from the subgenus of formula C-vi, the skilled medicinal chemist would have been motivated to select and make some compounds of the instant formula I because one would have expected those compounds to treat diseases mediated by p38 kinase as well.

Therefore, at the time that the invention was made, it would have been obvious to make and use compounds claimed herein in view of the teaching above


No pending claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

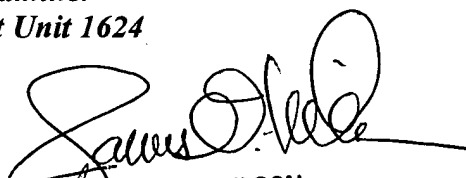
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

7-7-05


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